

REMARKS/ARGUMENTS

Claims 119-126 and 129-131 are currently pending in this application.

I. Claim Rejections - 35 U.S.C. §112, First Paragraph - Written Description

Claims 119-126 and 129-131 are rejected under 35 U.S.C. §112, first paragraph, because, according to Examiner, "the subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention." (Page 3 of the instant Office Action).

Applicants respectfully traverse this rejection to the pending claims. Applicants have discussed the claim rejections in great detail in their Response dated June 25, 2004 and maintain their position regarding this matter.

A. The Legal Test for Written Description

The well-established test for sufficiency of support under the written description requirement of 35 U.S.C. §112, first paragraph, is "whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language."^{1,2} The adequacy of written description support is a factual issue and is to be determined on a case-by-case basis.³ The factual determination in a written description analysis depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure.^{4,5}

¹ *In re Kaslow*, 707 F.2d 1366, 1374, 212 U.S.P.Q. 1089, 1096 (Fed. Cir. 1983).

² See also *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116 (Fed. Cir. 1991).

³ See e.g., *Vas-Cath*, 935 F.2d at 1563; 19 U.S.P.Q.2d at 1116.

⁴ *Union Oil v. Atlantic Richfield Co.*, 208 F.2d 989, 996 (Fed. Cir. 2000).

In *Environmental Designs, Ltd. v. Union Oil Co.*,⁶ the Federal Circuit held, "Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field."⁷ Further, the "hypothetical 'person having ordinary skill in the art' to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art."^{8,9}

B. The Disclosure Provides Sufficient Written Description for the Claimed Invention

Applicants respectfully submit that the instant specification evidences the actual reduction to practice of the amino acid sequence of SEQ ID NO: 351. Applicants also submit that the specification provides ample written support for determining percent sequence identity between two amino acid sequences (See pages 306-308, line 14 onwards). In fact, the specification teaches specific parameters to be associated with the term "percent identity" as applied to the present invention. The specification further provides detailed guidance as to changes that may be made to a PRO polypeptide without adversely affecting its activity. (Page 372, line 36 to page 373, line 17). This guidance includes a listing of exemplary and preferred substitutions for each of the twenty naturally occurring amino acids. (Table 6, page 372). Accordingly, one of skill in the art could identify whether the variant PRO1153

⁵ See also M.P.E.P. §2163 II(A).

⁶ 713 F.2d 693, 696, 218 U.S.P.Q. 865, 868 (Fed. Cir. 1983), cert. denied, 464 U.S. 1043 (1984).

⁷ See also M.P.E.P. §2141.03.

⁸ *Ex parte Hiyamizu*, 10 U.S.P.Q.2d 1393, 1394 (Bd. Pat. App. & Inter. 1988) (emphasis added).

⁹ See also M.P.E.P. §2141.03.

sequence falls within the parameters of the claimed invention. Once such an amino acid sequence was identified, the specification sets forth methods for making the amino acid sequences (see page 376, line 9) and methods of preparing the PRO polypeptides. (See Examples 140-143). Applicants submit that one skilled in the art would know that Applicants possessed these variants based on this disclosure.

Currently pending Claims 119-123 and 129-131 recite the functional recitation that the nucleic acid encoding the claimed polypeptides are amplified in lung tumors. Applicants further submit that the specification provides ample written support for detecting and quantifying amplification of such nucleic acids in several tumors and/or cell lines as described in Example 170. Example 170 of the present application provides step-by-step guidelines and protocols for the gene amplification assay. By following this disclosure, one skilled in the art would know that it is easy to test whether a gene encoding a variant PRO1153 protein is amplified in lung tumors by the methods set forth in Example 170.

More recently, in *Enzo Biochem., Inc. v. Genprobe, Inc.* 296 F.3d 1316 (Fed. Cir. 2002), the court adopted the standard that "the written description requirement can be met by 'showing that the invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" *Id.* at 1324. While the invention in *Enzo* was still a DNA, the holding has been treated as being applicable to proteins as well. Indeed, the court adopted the standard from the USPTO's Written Description Examination Guidelines, which apply to both proteins and nucleic acids.

Accordingly, current applicable case law holds that biological sequences are not adequately described solely by a description of their desired functional activities. The instant claims meet the standard set by the *Enzo* court in that the claimed sequences are defined not only by functional properties, but also by structural limitations. It is well established that a combination of functional and structural features may suffice to describe a claimed genus. "An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that Applicant was in possession of

the claimed invention, *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.¹⁰ Thus, the genus of polypeptides with at least 80-99% sequence identity to SEQ ID NO: 351, which possess the functional property of having a nucleic acid which is amplified in lung tumor would meet the requirement of 35 U.S.C. §112, first paragraph, as providing adequate written description. Accordingly, one skilled in the art would have known that Applicants had knowledge and possessed the claimed polypeptides with 80-99% sequence identity to SEQ ID NO: 351 whose encoding nucleic acids were amplified in lung tumors. The recited property of amplification of the encoding gene adds to the characterization of the claimed polypeptide sequences in a manner that one of skill in the art could readily assess and understand.

As discussed above, Applicants have recited structural features, namely, 80-99% sequence identity to SEQ ID NO: 351, which are common to the genus. Applicants have also provided guidance as to how to make the recited variants of SEQ ID NO: 351, **including listings of exemplary and preferred sequence substitutions**. The genus of claimed polypeptides is further defined by having a specific functional activity for the encoding nucleic acids. Accordingly, a description of the claimed genus has been achieved.

Accordingly, Applicants respectfully request reconsideration and reversal of the written description rejection of Claims 119-123 and 129-131 under 35 U.S.C. §112, first paragraph.

CONCLUSION

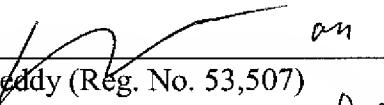
The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited. Should there be any further issues outstanding, the Examiner is invited to contact the undersigned attorney at the telephone number shown below.

¹⁰ M.P.E.P. §2163 II(A)(3)(a).

Please charge any additional fees, including fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (referencing Attorney's Docket No. 39780-2730 P1C31).

Respectfully submitted,

Date: July 24, 2007

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7/23/07 7:53 PM (39780.2730)